1. 510(k) Summary

MAY 2 8 2008

Submitter Information

A. Company Name: Baylis Medical Company Inc.

B. Company Address: 2645 Matheson Blvd. East
Mississauga, Ontario L4W 5S4
Canada

C. Company Phone: (905) 602-4875; ext: 252

D. Company Facsimile: (905) 602-5671

E. Contact Person: Meghal Khakhar

F. Summary Prepared: 13-December-2007

Device Identification

A. Device Trade Name: NRG Transseptal Needle

B. Device Common Name: Catheter, Septostomy

C. Classification Name: Septostomy catheter, 21 CFR 870.5175

D. Device Class: Class II

E. Device Code: DXF

Identification of Predicate Device

Predicate devices are the Toronto RF Septostomy Catheter (Baylis Medical Company, Inc.), which is cleared under 510(k) Premarket Notification Number K031949 and the Transseptal Needle/Trocar (Thomas Medical Products, Inc), which is cleared under the 510(k) Premarket Notification number K011727.

Device Description

The NRG Transseptal Needle is a sterile, single-use device that delivers radiofrequency (RF) energy to create an atrial septal defect in the heart.

Intended Use

Creation of an atrial septal defect in the heart. Secondary applications include transseptal heart access, monitoring intracardiac pressures, sampling blood, and infusing solutions.

Substantial Equivalence

The indications for use of the NRG Transseptal Needle are identical to the Toronto RF Septostomy Catheter. Both the devices are used in conjunction with the BMC Radio Frequency Perforation Generator (510(k) #: K013904) to create an atrial septal defect in the heart. Secondary applications include transseptal heart access, monitoring intracardiac pressures, sampling blood, and infusing solutions. The fundamental scientific technology of both these devices is also the same.

The indication for use of the NRG Transseptal Needle is substantially equivalent to the indication for use of the predicate Transseptal Needle/Trocar.

Device Testing

The NRG Transseptal Needle has been subjected to mechanical, electrical and simulated use bench testing to verify compliance with safety and performance requirements. The device will be validated for biocompatibility, sterilization and packaging.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2008

Baylis Medical Company Inc.
c/o Ms. Meghal Khakar
Manager, Regulatory and Scientific Affairs
2645 Matheson Blvd. East
Mississauga, Ontario,
Canada, L4W 5S4

Re: K073326
Trade/Device Name: NRG Transseptal Needle
Regulation Number: 21 CFR 870.5175
Regulation Name: Catheter, Septostomy
Regulatory Class: Class II
Product Code: DXF
Dated: April 28, 2008
Received: April 30, 2008

Dear Ms. Khakar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073326

Device Name: NRG Transseptal Needle

Indications For Use:

Creation of an atrial septal defect in the heart. Secondary applications include transseptal heart access, monitoring intracardiac pressures, sampling blood, and infusing solutions.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Volmer

on Sign-Off)
n of Cardiovascular Devices

Number K073326